

K03 1929

JUL 08 2003



510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:
May 22, 2003

Submitter's Information: 21 CFR 807.92(a)(1)
WIDE Corporation
Mr. YS Lim, President & CEO
576-5 Miwon-Ri, Miwon-Myun, Cheongwon-Gun
Chung, Korea 363-874

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)
Trade Name: 5MP TFT LCD Monitor System IF2105A™ by WIDE Corporation
Common Name: Picture Archiving Communications System
Device Classification: 892.2050
Name: System, Image Processing

Predicate Device: 21 CFR 807.92(a)(3)

| | |
|----------------------------|---|
| Device Classification Name | SYSTEM, IMAGE PROCESSING, RADIOLOGICAL |
| Regulation Number | 892.2050 |
| 510(k) Number | K023341 |
| Device Name | CORNIS 5MP MEDICAL FLAT PANEL DISPLAY SYSTEM |
| Applicant | BARCO NV P.O. BOX 12038 LA JOLLA, CA 92039 2038 |
| Product Code | LLZ |
| Date Received | 10/07/2002 |
| Decision Date | 12/23/2002 |

Device Description: 21 CFR 807.92(a)(4)

The 5MP TFT LCD Monitor System IF2105A™ is a flat panel hi-resolution LCD monitor system for displaying medical images. The system consists of a state-of-the-art LCD monitor and a high-resolution graphic control board that connects to a PACS workstation for grayscale image display. The WIDE controller board is installed into the PACS workstation computer or other computer system used to display PACS medical images.



Indications for Use: 21 CFR 807 92(a)(5)

The *5MP TFT LCD Monitor System IF2105A™* is intended to be used in displaying and viewing medical images for review and analysis by trained medical practitioners.

Technological Characteristics: 21 CFR 807 92(a)(6)

The device is an image display system consisting of computer software and components. The device does not contact the patient, nor does it control any life sustaining devices. A physician or trained medical practitioner provides ample opportunity for competent human intervention to interpret images and information being displayed.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for the *5MP TFT LCD Monitor System IF2105A™* contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device.

The *5MP TFT LCD Monitor System IF2105A™* will be manufactured by WIDE Corporation in accordance with the voluntary and safety standards, i.e. Safety / Immunity UL2601-1/EN60601-1 / IEC601-1, FCC Class B, CE, VCC, UL 950, cUL2601-1, CE Mark EMC/IEC = VCCI, CE, MIC FCC Class B digital device, pursuant to Part 15.

The submission contains the results of a hazard analysis and the potential hazards have been classified as Minor.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 08 2003

WIDE Corporation
% Mr. Ned Devine
Responsible Third Party Official
Entela, Inc.
3033 Madison Ave. SE
GRAND RAPIDS MI 49548

Re: K031929
Trade/Device Name: SMP TFT Monitor System
IF2105A™ by WIDE Corporation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and
communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: June 12, 2003
Received: June 23, 2003

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

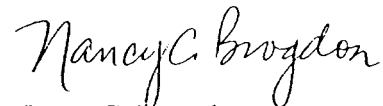
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

| | |
|----------------------------------|----------------|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

(Indications for Use Form)

510(k) Number: K031929

Device Name:

5MP TFT LCD Monitor System IF2105A™ by WIDE Corporation

Indications for Use:

The *5MP TFT LCD Monitor System IF2105A™* is intended to be used in displaying and viewing medical images for review and analysis by trained medical practitioners.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

OR

Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Syron
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031929